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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,593	07/23/1999	Robert I. Garver	JHV-009.01	3021

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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/359,593

Applicant(s)

GARVER ET AL.

Examiner

Quang Nguyen, Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☒ This action is **FINAL**.
- 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,9-19,21-26,28-33,35-38,40 and 42-50 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28,29 and 48 is/are rejected.
- 7) ☒ Claim(s) 50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 - Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 - Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some * c) ☐ None of:
 - 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 - Paper No(s)/Mail Date 2/27/04.
- 4) ☐ Interview Summary (PTO-413)
 - Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed on 2/27/04 has been entered.

Amended claims 1, 4-6, 9-19, 21-26, 28-33, 35-38, 40, 42-50 are pending in the present application.

Response to Applicants' amendment

The rejections in the previous Office Action mailed on 9/25/03 are withdrawn in light of Applicants' amendment.

Claim Objections

Claim 50 is objected to because the phrase "providing the said cancer cell" is not grammatically correct. Examiner suggests the phrase - - providing said cancer cell - - for overcoming this objection. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new ground of rejection necessitated by Applicant's amendment.**

Claim 28 is vague and indefinite in that the metes and bounds of the term "derived from" are unclear. It is unclear the nature and number of steps required to obtain a "derivative" of the delivery agent. The term implies a number of different steps that may or may not result in a change in the functional characteristics of the delivery agent from the source that it is "derived from". It would be remedial to amend the claim language to use the term - - obtained from - -, which implies a more direct method of acquiring human cells.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathiowitz et al. (WO 95/24929; IDS). **This is a new ground of rejection necessitated by Applicant's amendment.**

Mathiowitz et al. disclose a polymeric gene delivery system comprising a gene under a control of an appropriate promoter for expression in a particular cell type being encapsulated or dispersed within a biocompatible polymeric matrix, wherein the matrix is in the form of a microsphere and wherein the gene is able to diffuse out of the matrix over an extended period of time (page 5, lines 15-30). Mathiowitz et al. also teach that the gene can be incorporated directly into the polymer, or first incorporated into another

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material enhancing penetration of the DNA through the cell wall, such as liposomes or surfactants (page 5, lines 30-35). The gene can be delivered in the form of viral vectors (see page 16, under the section entitled "Biological vectors"). Among various microspheres' preparations, Mathiowitz et al. teach that carboxymethylcellulose microspheres are prepared by dissolving the polymer in an acid solution and precipitating the microspheres with lead ions (see page 13, lines 13-35). It is apparent that the carboxymethylcellulose microspheres of Mathiowitz et al. are simple coacervate microspheres which are defined as a single kind of hydrophilic material that is caused to emerge from solution by the addition of a phase-separation-inducing substance (see instant specification, page 18, lines 8-10), and that lead ions or lead nitrate would inherently crosslink the carboxymethylcellulose microspheres. Additionally, Mathiowitz et al. disclose that the polymeric microparticles or microspheres can be administered by injection, infusion, implantation (page 19, lines 14-20).

Accordingly, the gene delivery system taught by Mathiowitz et al. meets every limitation of the instant claims. Therefore, the reference anticipates the instant claims.

Conclusion

Claims 1, 4-6, 9-19, 21-26, 30-33, 35-38, 40, 42-47 and 49 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

Quang Nguyen, Ph.D.


DAVID GUZO
PRIMARY EXAMINER
8-1-11